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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,050	12/31/2001	Gregory Collier	12785	2282

7590 04/06/2006

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EXAMINER	
SAOUD, CHRISTINE J	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/039,050	COLLIER ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2005 and 03 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *90-93 and 95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *90-93 and 95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response received 07 November 2005 has been entered. It is noted that the response was not complete. The rejection under 35 USC 102(e) over Rosen et al. was not addressed. Applicant indicated that they would "address the rejection in a supplemental response".

Applicant is directed to 37 CFR 1.111(b) which states "[t]he reply by the applicant or patent owner must be reduced to a writing which distinctly and specifically points out the supposed errors in the examiner's action and must reply to every ground of objection and rejection in the prior Office action". Applicant is also directed to 37 CFR 1.111(a)(2) which states that supplemental replies will not be entered as a matter of right and will be clearly limited to cancellation of a claim, adoption of the examiner's suggestions, placement of the application in condition for allowance, reply to an Office requirement made after the first reply was filed, correction of informalities or simplification of issues for appeal.

Applicant's first response was not complete. Applicant did not specifically address the rejection of the claims under 102(e). Applicant's remedy is not to file a supplemental response – Applicant should request a suspension of the application if time is needed to obtain a declaration to overcome the rejection of record. Any further response which is not complete will be held as non-responsive. Any additional supplemental responses which do not meet the requirements of 37 CFR 1.111(a)(2) will not be entered.

Response to Amendment

Claims 1-89 have been canceled and claims 90-95 have been added in the response filed 07 November 2005. Claims 90-95 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 07 November 2005 and 03 January 2006 have been fully considered but they are not deemed to be persuasive.

Applicant's petition filed under 37 C.F.R. § 1.78(a)(6) on 07 November 2005 has been received and reviewed. The petition has been granted.

Specification

Applicant's amendment to the specification is noted. However, the amendment to the Drawing sheets and the Brief Description of the Drawings is not sufficient to meet the requirements of 37 CFR 1.84(u)(1) which states "Partial views intended to form one complete view, on one or several sheets, must be identified by the same number followed by **a capital letter**" (emphasis added). Correction is required. The objection to the drawings is maintained.

35 U.S.C. § 101

Claims 90-95 are rejected under 35 U.S.C. 101 for the reasons of record as applied to claims 1. 10-13, 18-20, 50, 59-62 and 67-69 in the Office action mailed 04 May 2005 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.

Applicant argues at page 6 of the response that the claimed "B55" molecule is specifically associated with insulin resistance and type 2 diabetes. Applicant asserts that the data in the specification "demonstrate that B55 acts in a protective manner in these tissues, and is required for the body to adequately cope with stresses such as food deprivation". Applicant also asserts that the lack of B55 during the fed state in insulin resistant and type 2 diabetic animals, is associated with impaired glucose metabolism. Therefore, Applicant concludes that "increased expression of B55 would be beneficial for the treatment of insulin resistance and type 2 diabetes".

Applicant's arguments have been fully considered, but are not found persuasive. The fact that the expression of B55 is altered during different states of fasting and feeding is noted, but this in of itself does not implicate the molecule in any particular disease state or imply a role in glucose metabolism. If all protein expression were measured, there would be hundreds of proteins for which protein expression was increased, just as there would be hundreds of proteins for which protein expression was decreased. The only way to determine if a given protein is involved in insulin resistance or type 2 diabetes is to test the protein to see if it actually affects glucose metabolism, or some other measure of insulin resistance and/or type 2 diabetes. Applicant asserts at

page 7 of the response that the claimed invention has therapeutic applications in insulin resistance and type 2 diabetes. However, the instant specification fails to teach that the claimed invention has anything to do with insulin resistance and/or type 2 diabetes. The data presented in the instant specification were limited to expression of the B55 gene under conditions of feeding and fasting, and lean animals versus obese animals. The specification specifically states that in the rats used, only 1/3 of the rats which are overfed develop NIDDM (i.e. type 2 diabetes) (see page 16 of the specification, final paragraph). The data presented do not distinguish those rats which are obese without NIDDM from those rats which are obese and have NIDDM. Therefore, assertions regarding diabetes are questionable because it does not appear that the instant specification ever distinguished the obese animals from those that were considered clinically diabetic.

As pointed out previously, the claimed invention is very similar to a family of proteins which are called "selenoproteins", which thought to be responsible for most biomedical effects of dietary selenium. However, there is no evidence of record which would suggest that the claimed invention, or selenoproteins, have anything to do with obesity, anorexia, diabetes or energy imbalance. There is no teaching in the prior art that these proteins are involved in glucose metabolism, insulin resistance or type 2 diabetes. The skilled artisan at the time the instant invention was made would not reasonably conclude that the claimed invention is specifically associated with insulin resistance and type 2 diabetes based on the expression data of the instant specification. This is because these conditions affect a number of proteins for a number

of reasons, not all of which have to do with the condition of insulin resistance or type 2 diabetes. Furthermore, the fact that the claimed invention appears to be a selenoprotein is suggestive that the claimed invention may have some role in the regulation of selenium, which has not been shown to have any relationship to insulin resistance or type 2 diabetes. The specification fails to establish a nexus between the claimed invention and obesity, anorexia, diabetes or energy imbalance, and therefore, the asserted utilities related to such are not substantial.

Claims 90-93 and 95 are also rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the previous Office action as applied to claims 1, 10-13, 18-20, 50, 59-62, 67-69. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above and in the previous Office action, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Claim Rejections - 35 USC § 112

Claim 90-93 and 95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record as applied to the previously filed claims and for those reasons provided below. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 90 recites the limitation "wherein increased expression of said nucleic acid molecule is useful in the treatment of diabetes". However, there is no written descriptive support for this limitation, either literally or in any other sense. A review of pages 34 and 37, cited by Applicant, does not reveal this language or any disclosure of this association. Furthermore, there is clearly no disclosure of any molecule having at least 90% similarity to SEQ ID NO:6 as having any particular activity or association with being useful in the treatment of diabetes. The specification may disclose that molecules having 90% similarity are within the scope of the invention, but there is no explicit statement that they are to possess any particular kind of activity, absent evidence to the contrary. Therefore, the claims are considered new matter.

Applicant's arguments are noted, however, in light of the new ground of rejection, necessitated by Applicant's amendment, these arguments are moot. Applicant should note for further reference, the limitation of "increased expression of said nucleic acid molecule is useful in the treatment of diabetes" is not being considered a functional limitation. This is because there is no function associated with it. The nebulus recitation of "useful in the treatment of diabetes" has no particular meaning and the specification fails to disclose what such a use would be. What is really being claimed is a characteristic of the nucleic acid – i.e. that its expression is increased, which is not a functional limitation.

Claims 90-93 and 95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858, F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are drawn to nucleic acids encoding a polypeptide having at least 90% amino acid sequence identity to the polypeptide of SEQ ID NO:6. There is no functional limitation in the claims for the encoded protein (or for the nucleic acid for the reasons stated above and/or below). The claims encompass an unreasonable number of inoperative polypeptides, which the skilled artisan would not know how to use. The claims require no function for the polypeptides which are encoded. As opposed to the claims, what is disclosed about SEQ ID NO:6 is narrow: a single polypeptide of SEQ ID NO:6 encoded by a nucleic acid of SEQ ID NO:5, wherein the nucleic acid of SEQ ID NO:5 is "differentially expressed in liver tissue of obese animals compared to lean animals". The skill in the art does not make up for the deficiencies in the specification as to the function of the encoded protein. There are no working examples of polypeptides less than 100% identical to the polypeptide of SEQ ID NO:6. The

specification does not provide guidance for using polypeptide related to (i.e., 90% similarity) SEQ ID NO:6 and there is no disclosed function for the protein of SEQ ID NO:6. The claims are broad because they do not require the encoded polypeptide to be identical to the disclosed sequence and because the claims have no functional limitations related to the encoded protein or the nucleic acid.

For these reasons, which include the complexity and unpredictability of the nature of the invention and the lack of knowledge about the function(s) of encompassed polypeptides structurally related to the amino acid sequence of SEQ ID NO:6, the one example of SEQ ID NO:6 (protein) and SEQ ID NO:5 (nucleic acid), the lack of direction or guidance for using the polypeptide of SEQ ID NO:6 or polypeptides which are structurally related by amino acid sequence, and the breadth of the claims for structure without function, it would require undue experimentation to use the invention commensurate in scope with the claims.

Claims 90-93 and 95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 90 recites "wherein increased expression of said nucleic acid molecule is useful in the treatment of diabetes". However, there is no clear indication of what said "useful in the treatment of diabetes" is meant to encompass. Therefore, it would not be clear what kind of molecules are covered by the claims. There is no disclosure of any improvement of a diabetic state by increasing the expression of this nucleic acid. There

is no disclosure of the protein encoded by this nucleic acid being administered in the diabetic condition, and therefore, there is no disclosure as to the biological activity of the encoded protein as it relates to treatment of diabetes. Therefore, the claims are indefinite.

Claim Rejections - 35 USC § 102

The Declaration filed on 03 January 2006 under 37 CFR 1.131 is sufficient to overcome the Rosen et al. reference.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD
PRIMARY EXAMINER
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